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Short Communication

Direct-to-PCR Viral Diagnostic Testing, A Model to Reduce Cost and Increase Access for Underserved Communities

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ABSTRACT

The global COVID-19 pandemic has driven rapid innovation in everything from therapeutics to diagnostics surrounding SARS-CoV-2 infections, while highlighting the need for cost efficient and accessible developments in these fields. Novel innovation that increases access to diagnostic testing in resource limited areas is still critical in supporting the response to COVID-19. In this manuscript we discuss the applications of a direct-to-PCR approach for SARS-CoV-2 detection which may serve as a viable option for addressing the need of rapid and accurate diagnostics in resource limited communities.

Keywords: COVID-19 Diagnostics; PCR Diagnostics; Viral Detection; Viral Diagnostics; COVID-19 Testing

DESCRIPTION

In October of 2020, the global community began to experience a second wave of the COVID-19 global pandemic, with increases in total daily cases, hospitalizations, and fatalities seen across the United States and Europe [1]. As cases rise, testing and surveillance measures continue to prove pivotal in the fight to control the spread of SARS-CoV-2 throughout a community [2]. Until an effective vaccine has been widely distributed, accurate and accessible testing measures are the corner stone of any effective public health response to this virus [2,3]. While the global community has worked diligently to increase testing capacity many communities are still left without adequate access to crucial viral diagnostic testing, leaving them at increased risk for disease propagation throughout their community. There is an urgent need for innovation in accurate diagnostic testing to support the public health mitigation efforts surrounding COVID-19 [3,4]. Improving access to testing through simplifying the equipment and workflow needed, reducing cost, and decreasing the total time required to complete a test while maintaining diagnostic sensitivity and specificity is a crucial step in public health efforts against COVID-19.

Morehouse, et al. in their recent manuscript "A novel two-step, direct-to-PCR method for virus detection off swabs using human coronavirus 229E" published in Virology Journal propose a method of direct-to-PCR diagnostic testing that could serve as a model for increasing viral diagnostic testing capacity to rural and underserved communities at substantially lower costs when compared to the traditional fully automated testing set up [5]. The current model for viral diagnostics using nasopharyngeal swabs relies on three major steps, sample collection, nucleic acid extraction, and PCR-based detection [4]. Of these steps, the nucleic acid extraction step has become the lynchpin in many detection methods during the COVID-19 pandemic due to reliance on multiple chemical reagents and laboratory plastics that have become increasingly scarce as the global supply chain has been stressed [6]. In this publication, Morehouse et. al. demonstrate a method of viral detection that bypasses the genetic extraction steps involved in the traditional PCR-based detection workflow and replaces it with 30 seconds of homogenization where the mechanical forces lyse 98% of the viral particle and provide adequate exposure of the RNA to allow the resulting lysate to be placed directly into a PCR reaction for accurate viral detection [5]. With a sensitivity of 96.4% when detecting human coronavirus 229E (HCoV-229E) at clinical viral loads, this study proves that the direct-to-PCR methodology can provide a successful alternative to traditional extraction-based workflows at a fraction of the cost [5]. For under $50,000 USD any hospital or community health organization can purchase a homogenizer and thermocycler, and the required PCR reagents to set up the process outlined in this manuscript – this is in comparison the hundreds of

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thousands of dollars it costs to purchase fully automated machines to carry out the genetic extraction steps of the traditional workflow on top of the reagent heavy extraction kits themselves. While the traditional model and all of the automation it has been outfitted with are critical in large scale testing capacity for large hospitals and major cities, the authors are proposing that the direct-to-PCR method discussed should be further examined as an alternative to allow for local diagnostic testing to be established in rural and underserved communities. These communities do not have the volume of large hospitals or major metropolitan areas but still require adequate testing in their community to assist in local public health efforts against COVID-19, for which this cheaper, yet still accurate, model of testing may prove ideal.

As the global community continues to battle the COVID-19 pandemic, innovation in all aspects of the response is important – while ensuring that innovation is accessible to all communities affected by this pandemic is paramount [2,6]. With SARS-CoV-2 infecting communities from wealthy urban areas in developed countries to rural and underserved areas in developing nations, it is our responsibility as scientists and clinicians to ensure that our ideas of innovation to combat this virus are paired with discussions on accessibility to this innovation on a global scale. There is no one right answer to how we can provide adequate diagnostic testing for COVID-19, but there is a need to continue to be open to all possibilities and examine novel approaches as they become available.

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CONFLICT OF INTEREST

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